

### **REMARKS**

Claims 31-36 are pending in this application. Applicant respectfully requests reconsideration of this application and submit the following remarks.

### **DRAWINGS**

The drawings were objected to for allegedly not showing the steps recited in the method of claim 31. Applicant respectfully submits that each step of claim 31 is shown in the drawings of the original specification. Claim 31 recites: “delivering a first electrical stimulus to an intralaminar nuclei of a brain.” Accordingly, FIG. 3 illustrates the intralaminar nuclei of a brain.

Claim 31 further recites: “delivering a second electrical stimulus to another area of the brain.” Accordingly, FIG. 1 illustrates various other parts of the brain that are not the intralaminar nuclei. For at least these reasons, Applicant respectfully submits that the appropriate drawings have been furnished, and requests that the objections to the drawings be withdrawn.

### **SPECIFICATION**

The specification was objected to because the statement “electrical stimulation can also extend to other regions of the brain” (page 22, lns. 16-18) allegedly contradicts the statement “the electrical stimulation is applied only to the patient’s intralaminar nuclei or portion thereof without stimulating other regions of the patient’s brain (page 22, lns. 18-19).

Applicant respectfully submits that these statements are not contradictory when they are read in their entirety as follows: “In addition to being applied to the patient’s intralaminar nuclei or portion thereof, the electrical stimulation can also extend to other regions of the brain. Preferably, the electrical stimulation is applied only to the patient’s intralaminar nuclei or portion thereof without stimulating other regions of the patient’s brain.” (see page 22, lns. 16-19).

Thus, these two sentences indicate that in the preferred case, electrical stimulation is limited to the ILN or portion thereof, but in other cases, the electrical stimulation can extend to other sites as well. As such, the two sentences are not contradictory, but together serve to clarify the scope of the invention.

## REJECTIONS UNDER § 112

Claims 31-36 were rejected for allegedly be non-compliant with the enablement requirement under § 112, first paragraph. Applicant requests reconsideration of these rejections.

Independent claim 31 recites: “delivering a first electrical stimulus to an intralaminar nuclei of a brain of a mammal having a psychiatric disorder; and delivering a second electrical stimulus to another area of the brain, wherein the another area of the brain is not the intralaminar nuclei.” Applicant submits that the specification is enabling because it provides ample guidance for a person skilled in neurosurgery to perform the claimed method.

MPEP § 2164 states: “The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention.” In the test for enablement, MPEP § 2162.01 states: “A patent need not teach, and preferably omits, what is well known in the art.” Indeed, the specification does not attempt to teach how to perform neurosurgery, which is a highly specialized skill possessed primarily by neurosurgeons. What the specification does do is provide ample guidance for a person of ordinary skill in neurosurgery to perform the claimed method.

The specification provides a detailed description of how electrical stimulation may be provided to a target site in the brain. Page 15, lns. 4-19 describes how target sites in the brain are stereotactically mapped using fixed head frames and radiologic imaging, such as MRI, so that the surgeon is able to target any region in the mapped space with high precision (e.g., within 1 mm). Page 15, lns. 20-29 describes how the initial steps in the surgical procedure are performed. Page 16, lns. 1-9 describes how the physiological localization within the brain using single-cell microelectrode recordings are performed for definitive target determination. Page 16, lns. 10-21 describes one example of an electrode and how it is then implanted. Page 17, ln. 16 – page 18, ln. 7 describes how the electrical stimulation may be applied, including frequency, voltage, pulse width, and polarity.

Based on this guidance for electrical stimulation at one target site in the brain, a person of ordinary skill in the art could apply the same technique to deliver a second electrical stimulus to another area of the brain, as suggested by the specification: “In addition to being applied to the patient’s intralaminar nuclei or portion thereof, the electrical stimulation can also extend to other

regions of the brain” (page 22, lns. 16-18). For example, the neurosurgeon may simply place another identical electrode at another site in the brain.

Thus, the specification provides ample guidance for delivering a first stimulus and a second stimulus to the brain. For at least these reasons, Applicant submits that claim 31 and dependent claims 32-36 are in compliance with the enablement requirement under § 112, first paragraph.

Applicant also address the following comments in the Office Action, as reproduced below. On page 4, the Office Action states:

Examiner disagrees. Page 8, lines 28-29 of the specification states “operating the device to modulate the intra-laminar nuclei....to affect the disorder associated with the specific area of the brain” wherein this specific area of the brain “may be different from the intra-laminar nuclei” and that “this specific area may be selected from the group consisting of the pre-frontal cortex, orbitofrontal cortex, ...” etc. Based upon this statement, only one area of the brain is being stimulated – the intra-laminar nuclei – in order to affect a different “specific area” of the brain.

This portion of the specification (p. 8, lns. 28-29) describes a particular embodiment of the present invention. In its entirety, the specification describes several other embodiments, including the embodiment where: “In addition to being applied to the patient’s intralaminar nuclei or portion thereof, the electrical stimulation can also extend to other regions of the brain” (page 22, lns. 16-18) and also: “Where two or more subdivisions of the patient’s brain (e.g., intralaminar nuclei) are electrically stimulated periodically and at the same frequency, such stimulation can be completely in phase, partially in phase and partially out of phase, or completely out of phase” (page 29, lns. 23-25). It is embodiments such as these that are the subject matter of claim 31.

Also on page 4, the Office Action states:

Page 22, lines 10-18 state that “The electrical stimulation” may be applied to “the patient’s entire nuclei....or subsections such as to one or more portions of the patient’s intra-laminar nuclei”.

Note that the language “The electrical stimulation” appears to *refer to only one stimulus, not two*, as recited in claim 31. And, if two electrical stimulus pulses were to be delivered, the specification only specifically states that this may occur in “one or more portions of the intra-laminar nuclei”. In addition, applicant’s claim 31 contradicts p.22, lines 18-19 of the specification, which states “Preferably, the electrical stimulation is applied *only to the patient’s intra-laminar nuclei or portion thereof without stimulating other regions of the patient’s brain*”.

This portion of the specification (page 22, lns. 10-18) also describes a particular embodiment of the present invention. Reading further in the same paragraph (at lns. 16-18) reveals an embodiment of claim 31: “In addition to being applied to the patient’s intralaminar nuclei or portion thereof, the electrical stimulation can also extend to other regions of the brain.” Also, as explained above, these statements in the specification are not contradictory.

CONCLUSION

Applicant respectfully submits that the present application is in condition for allowance. The Examiner is invited to contact Applicant's representative to discuss any issue that would expedite allowance of this application.

The Commissioner is authorized to charge all required fees, fees under § 1.17, or all required extension of time fees, or to credit any overpayment to Deposit Account No. 11-0600 (Kenyon & Kenyon LLP).

Respectfully submitted,

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